

# EXHIBIT 13

1 UNITED STATES DISTRICT COURT  
2 DISTRICT OF MINNESOTA  
3

4 In re Bair Hugger Forced Air ) MDL No. 15-2666  
Warming Products Liability ) (JNE/FLN)  
5 Litigation, ) VOLUME I  
 ) PAGES 1-210  
6  
7  
8  
9  
10  
11  
12

13 VIDEOTAPED DEPOSITION OF JONATHAN SAMET, M.D.  
14 LOS ANGELES, CALIFORNIA  
15 TUESDAY, JULY 11, 2017  
16  
17  
18  
19  
20  
21  
22  
23

24 Job No. 124786  
25 DORIEN SAITO, CSR 12568, CLR

UNITED STATES DISTRICT COURT  
DISTRICT OF MINNESOTA

In re Bair Hugger Forced Air ) MDL No. 15-2666  
Warming Products Liability ) (JNE/FLN)  
Litigation, )  
)

Videotaped deposition of JONATHAN SAMET,  
M.D., taken on behalf of Defendants, at 601  
South Figueroa Street, Suite 2500, Los  
Angeles, California 90071, commencing at  
10:57 a.m., Tuesday, July 11, 2017, before  
Dorien Saito, CSR 12568, CLR.

A P P E A R A N C E S :

FOR PLAINTIFFS:

CIRESI CONLIN  
By: JAN CONLIN, ESQ.  
225 South 6th Street  
Minneapolis, Minnesota 55402

FOR DEFENDANTS:

BLACKWELL BURKE  
By: COREY GORDON, ESQ.  
431 South Seventh Street  
Minneapolis, Minnesota 55415

ALSO PRESENT:

JORDAN LEADS, Videographer  
JONATHAN BORAK  
MORDECAI BOONE

I N D E X

W I T N E S S :

	PAGE
JONATHAN SAMET, M.D.	8
EXAMINATION BY MR. GORDON	
AFTERNOON SESSION:	
EXAMINATION BY MR. GORDON	97

INFORMATION REQUESTED:  
(NONE)

QUESTIONS INSTRUCTED NOT TO ANSWER:  
(NONE)

E X H I B I T S :

NUMBER	DESCRIPTION	PAGE
Exhibit 1	Expert report of Jonathan M. Samet M.D., M.S. dated March 30, 2017	28
Exhibit 2	Article entitled "Arthroplasty, Forced-air warming and ultra-clean ventilation do not mix"	61
Exhibit 3	Expert Report of Theodore R. Holford, Ph.D.	71
Exhibit 4	Publication from the CDC regarding the health consequences of smoking	84
Exhibit 5	Raw case data (No infection or infection)	128

I N D E X (continued)

E X H I B I T S :

NUMBER	DESCRIPTION	PAGE
Exhibit 6	Article entitled "Arthroplasty, Forced-air warming and ultra-clean ventilation do not mix"	129
Exhibit 7	Email from Mark Albrecht to Mike Reed, et al. With cc to Scott Augustine dated January 31, 2011	132
Exhibit 8	Email from Mark Albrecht to Mike Reed with cc to Scott Augustine dated November 1, 2010	136
Exhibit 9	Spreadsheet	137
Exhibit 10	Document entitled "Implementing effective SSI surveillance"	141
Exhibit 11	Trust Wide Surgical Site Infection Intervention Timeline for Orthopaedic THR & TKR surgery (including revision) and Repair Neck of Femur	142
Exhibit 12	Email from Mar Albrecht to Mike Reed and cc to Christopher Nachtsheim dated November 22, 2011	149
Exhibit 13	Document entitled "A Novel Approach to Assess the Effect of a Forced-air Patient Warming System on Increasing the Risk of Nosocomial Infections at the Surgical Wound Site" by Farhad Memarzadeh, Ph.D., P.E.	169

1	I N D E X (continued)	
2	E X H I B I T S :	
3	NUMBER	DESCRIPTION PAGE
4	Exhibit 14	Article entitled "Patient 182
5		Warming Excess Heat: The Effects
6		on Orthopedic Operating Room
7		Ventilation Performance" by
8		Kumar G. Belani, Mark Albrecht,
9		Paul McGovern and Christopher
10		Nachtsheim, Ph.D.
11	Exhibit 15	Article entitled "Forced-air 184
12		warming blowers: An evaluation
13		of filtration adequacy and
14		airborne contamination emissions
15		in the operating room" by Mark
16		Albrecht, Robert L. Gauthier,
17		M.D., Kumar Belani, Mark Litchy,
18		M.E. and David Leaper, M.D.
19	Exhibit 16	Article entitled "Arthroplasty, 186
20		Do forced air patient-warming
21		devices disrupt unidirectional
22		downward airflow? By A.J. Legg,
23		T. Cannon and A.J. Hamer
24	Exhibit 17	Article entitled "Arthroplasty, 188
25		Forced-air patient warming
		blankets disrupt unidirectional
		airflow" by A.J. Legg and A.J.
		Hamer
	Exhibit 18	Email from Mark Albrecht to 189
		Andrew Legg, M.D., Scott
		Augustine and Christopher
		Nachtsheim dated
		September 10, 2010
	Exhibit 19	Email from Mark Albrecht to Mike 197
		Reed and Paul McGovern dated
		July 9, 2010

1 on behalf of the plaintiffs from Ciresi Conlin.

2 THE VIDEOGRAPHER: Thank you.

3 THE REPORTER: Would you raise your right

4 hand.

5 THE WITNESS: (Complies.)

6 THE REPORTER: Do you so state under

7 penalty of perjury that the testimony you shall

8 give in your deposition shall be the truth, the

9 whole truth, and nothing but the truth?

10 THE WITNESS: Yes, I do.

11 \*\*\*

12 JONATHAN SAMET, M.D.,

13 having been duly administered an oath

14 in accordance with CCP 2094, was

15 examined and testified as follows:

16 \*\*\*

17 EXAMINATION

18 BY MR. GORDON:

19 Q Good morning, Dr. Samet.

20 A Good morning.

21 Q As you know from our brief introduction a

22 moment ago, my name is Corey Gordon. And I'll be

23 asking you some questions today about the expert

24 opinions you proffered in the multidistrict litigation

25 pending.

1 LOS ANGELES, CALIFORNIA; TUESDAY, JULY 11, 2017

2 10:57 A.M.

3 -0o0-

4 \*\*\*

5 THE VIDEOGRAPHER: This is the start of

6 tape labelled Number 1 of the videotaped

7 deposition of Dr. Jonathan Samet in re Bair Hugger

8 Forced Air Warming Products Liability Litigation

9 in the United States District Court, District of

10 Minnesota, Case Number 15-2666(JNE/FLN).

11 This deposition is being held at

12 601 South Figueroa Street, Suite 2500,

13 Los Angeles, California, on Tuesday, July 11 of

14 2017 at approximately 10:58 a.m.

15 My name is Jordan Leads from TSG

16 Reporting, Incorporated, and I'm the legal video

17 specialist.

18 The court reporter is Dorien Saito in

19 association with TSG Reporting.

20 Will counsel please introduce yourselves.

21 MR. GORDON: Corey Gordon on behalf of

22 the defendants 3M Alizant. Also with me today is

23 Mordecai Boone, the in-house counsel #M as well as

24 Professor Jonathan Borak, experts.

25 MS. CONLIN: Jan Conlin and Mike Sacchet

1 So you've had your deposition taken several

2 times before; is that correct?

3 A I have in the past, yes.

4 Q And you've testified as an expert witness in

5 litigation before; is that correct?

6 A That's correct.

7 Q Now, I know you've testified as an expert in

8 several cases involving the claims being made against

9 the tobacco industry.

10 Is that correct?

11 A That's correct.

12 Q Have you testified as an expert or offered --

13 well, strike that.

14 Have you testified as an expert in any cases

15 involving anything other than tobacco-related claims?

16 A To my recollection, solely tobacco.

17 Q And have you offered opinions maybe that

18 didn't lead to you ever having to give a deposition or

19 testimony in court outside of the tobacco arena?

20 A I would suspect if I looked back across a

21 long career, I've had lawyers contact me about a

22 variety of matters. At most these resulted in

23 conversations but nothing further.

24 Q I'm guessing that you've probably been

25 frequently asked by lawyers to serve as a consultant

Page 62

1 Q And one of the reasons you conclude that the  
2 odds ratio that is reported, the relative risk that is  
3 reported is not influenced by any confounders is the  
4 fact that it is a strong association; is that correct?

5 A In part, yes.

6 Q Anywhere in part.

7 And tell me -- well, strike that.

8 Would you -- would you agree that -- that  
9 generally in the epidemiological literature,  
10 associations are usually categorized as weak,  
11 moderate, or strong?

12 A I -- people may do that. I personally don't.

13 Q You don't?

14 A No.

15 Q Okay. So is it binary for you? Something  
16 is -- an association is either strong or it's not  
17 strong?

18 A I think the numbers speak for themselves.

19 Q Well, what's a strong association?

20 A I -- I -- again, I rely not on adjective  
21 descriptors in -- in general but on the description of  
22 what the actual estimate is.

23 Q So would you rely on 3. -- a relative risk of  
24 3.8 as a -- as evidence of a strong association? That  
25 a relative risk of 3.8, in your opinion, constitutes

Page 63

1 based on association; is that right?

2 A Actually, I'm not sure I applied the word  
3 "strong." I'd have to look through my report.  
4 (Witness reviewing document.)

5 THE WITNESS: I discussed strength of  
6 association on page 16. I did not -- I said  
7 moderately. It says "moderately strong."  
8 Page 16.

9 BY MR. GORDON:

10 Q Moderately strong association.

11 Okay. Tell me, in your stratification of --  
12 of a strength of association, what -- what are the  
13 different categories? Is there --

14 A Again --

15 Q Is it moderately strong? You know, strongly  
16 strong? Weakly strong? I -- I'm not --

17 A That's why. I just can't give you a  
18 Jonathan Samet classification where I have a set of  
19 standard descriptors I would use.

20 Q Okay. But to you, 3.8 is moderately strong?

21 A Correct.

22 Q And would -- would you consider a 3. -- if  
23 somebody said "Dr. Samet, I've got a" -- "got some  
24 observation study that concluded that there was a  
25 relative risk of 3.7," do you think that kind of

Page 64

1 eliminates the possibility of -- of confounders?  
2 Would you say that 3.7 was a moderately strong  
3 association that would give you reason to -- a comfort  
4 level that there -- that that's not a result of  
5 confounding?

6 A I -- it's not so simple a question. It  
7 really depends -- it depends on the relevant  
8 confounder set and how strong confounders might be  
9 as -- as risk factors for the outcome of it.

10 Q So it's not be the number in the abstract  
11 that allows to you decide whether it's a moderately  
12 strong association or not? There are some other  
13 factors that you consider in conjunction with the  
14 actual relative risk number?

15 A I'm sorry. You're speaking to the strength  
16 of the relative risk or confounding?

17 Q Well, I'm focusing on -- on page 16 where you  
18 say (reading):

19 "With respect to the Hill  
20 criteria" -- "Hill postulates, that  
21 with respect to strength of  
22 association, the available  
23 observational evidence indicates a  
24 moderately strong association."

25 And you discussed McGovern and say

Page 65

1 (reading):

2 "The relative risk is estimated  
3 at 3.8."

4 And, you know, I -- I'm -- I'm pretty  
5 sure I saw it somewhere else. You did link that.

6 Yeah, I -- I think what I was -- thank  
7 you for pointing me to that. What I was thinking  
8 of is on page 12 where you said that (reading):

9 "A more general argument  
10 against confounding can also be  
11 made. In setting aside whether the  
12 antibiotics and/or  
13 thromboprophylaxis were truly  
14 confounding, the magnitude of the  
15 association, 3.8 odds ratio  
16 reported by McGovern, et al.,  
17 deserves consideration."

18 You say that (reading):

19 "Such confounding is not only  
20 unlikely but is not supported by  
21 the evidence considered above and  
22 reviewed by Professor Nachtsheim  
23 and Drs. McGovern and Reed."

24 Right?

25 A Correct.

Page 122

1 infections in the reported surveillance period divided  
2 by total number of procedures performed during the  
3 period; right?

4 A Correct.

5 Q And in the McGovern paper, what was the rate  
6 for the HotDog only period?

7 (Witness reviewing document.)

8 THE WITNESS: I --

9 BY MR. GORDON:

10 Q If it's taking too long, it's on page 5042.

11 A 0.8.

12 Q And that's based on how many --

13 How -- how is that 0.8 derived?

14 A That is 3 over 268.

15 Q Okay. What was the rate for the HotDog only  
16 period?

17 A I'm sorry. That's -- that was the HotDog  
18 period.

19 Q I'm sorry. I misspoke.

20 What was the rate during the Bair Hugger  
21 period?

22 A 3.0.

23 Q 3.0?

24 A That's correct.

25 Q Okay. And what was the -- what were the --

Page 123

1 What was the equation that --

2 A Well, it's 32 over 1,034.

3 Q Okay. And so tell me how -- how the  
4 calculation gets to 3.1.

5 A Oh, it's calculated -- it's the odds ratio  
6 divided by 2. --

7 Q I -- I misspoke. 3.8; right? The average  
8 that you're using is 3.8; right?

9 A Correct.

10 Q Divide that 3 percent -- or 3.0 by 0.8;  
11 right?

12 A No. It's the odds ratio from the table.

13 Q Well, how -- how was that -- that 3.8 odds  
14 ratio derived?

15 A There's an underlying 2x2 table with warming  
16 device, yes/no; infection, yes/no. And then it's  
17 calculated as the odds ratio from the table.

18 Q But I'm just trying to understand, What --  
19 what are the numbers that are plugged in?

20 A The numbers are the -- sure. The numbers are  
21 the 321034 and the 3368.

22 Q Well, is -- is there any relationship between  
23 3.0 and 0.8 in terms of coming up with the odds ratio?

24 A The -- are you asking for how an object was  
25 calculated?

Page 124

1 Q Yeah.

2 A So it is -- it comes out of the table that  
3 describes. And it's simply the cross-product of the  
4 diagonals.

5 Q Does it have anything to do with the ratio of  
6 3.0 to 0.8?

7 A Well, the same -- the same numbers are -- the  
8 same numbers are involved, yes.

9 Q And that if that -- if the -- for example, if  
10 the 0.8 number were higher, the odds ratio would go  
11 down, wouldn't it?

12 A It would be a different data set, but yes.

13 Q Okay. Well, do you recall when you read  
14 Dr. Reed's testimony that he said that there was --  
15 that the numbers weren't quite correct, there was  
16 actually one more infection in each group?

17 A I'm aware of that discussion, yes.

18 Q Well, were you aware of it before you wrote  
19 your report?

20 A I don't think I was.

21 Q Okay. So you're aware of it now?

22 A I'm aware of it now.

23 Q You became aware of it because you read  
24 Dr. Holford's report?

25 A I -- probably Holford's report brought my

Page 125

1 attention to it.

2 Q So you hadn't read -- either hadn't read it  
3 or just --

4 A I -- you know, again, I -- I remember some  
5 discussion about data sets. And I don't know what is  
6 the, quote, "correct" -- "correct data set." But I'm  
7 aware that Reed commented about the data.

8 Q Okay. If you add one infection to each  
9 group, what happens to the odds ratio?

10 A That's -- you know, again, I mean, that's not  
11 a question that could be answered generically. I  
12 mean, if we calculate it here, I suspect that since 3  
13 is a very small number, adding 1 to make it 4 would  
14 lower the odds ratio.

15 Q Well, why don't you take a look at  
16 Dr. Holford's report here.

17 Is that Exhibit 4?

18 MS. CONLIN: Exhibit 3.

19 BY MR. GORDON:

20 Q 3. And if you'll look at page 3, Footnote 1.  
21 (Witness turning to page.)

22 BY MR. GORDON:

23 Q For the moment, I don't want to ask you about  
24 Dr. Holford's calculation based on his analysis of the  
25 data set and the -- all the other things. He's

Page 126

1 just -- Footnote 1 is just based on Dr. Reed's  
2 testimony that was one more infection in each group.

3 Do you have any reason to think that  
4 Professor Holford screwed up the calculations that he  
5 did there?

6 A Oh, he certainly did the calculations  
7 correctly.

8 Q Okay. And assuming those --

9 Well, first of all, do you have any reason to  
10 think that Dr. Reed testified inaccurately?

11 A I can't comment on that.

12 Q Okay. Well, if -- if -- if that testimony is  
13 accurate and Dr. Holford's calculations are accurate,  
14 the odds ratio would be 2.86; right?

15 A According to the calculation shown here, yes.

16 Q And the confidence interval would be 1.03 to  
17 8.33; right?

18 A As described here, yes.

19 Q Is that -- would you say that's a strong  
20 association or moderately strong association, one that  
21 would allow you to feel comfortable in saying there  
22 couldn't be any confounders that can account for this  
23 odds ratio?

24 A My only comment is 2.86 is lower than 3. --  
25 3.8.

Page 128

1 ratio would drop with the addition of one event to the  
2 HotDog period when there's very few events there.

3 MR. GORDON: What number are we on? 5.  
4 Let me show you what's been marked as Exhibit 5.  
5 This was previously part of -- of the McGovern  
6 exhibits, which did not have unique exhibit  
7 numbers for a multiseries of pages.

8 (The aforementioned document was  
9 marked Exhibit 5 for identification  
10 by the reporter.)

11 BY MR. GORDON:

12 Q But you did indicate that you had available  
13 to you the McGovern testimony and the McGovern  
14 exhibits, and there was some discussion -- there was  
15 some testimony about this.

16 Do you recall seeing this, Exhibit 5, prior  
17 to today?

18 A I think I've seen this.

19 Is this the sixty-day moving average data?

20 Q No. That would be Professor Holford's  
21 report. This is --

22 MS. CONLIN: This is Exhibit 21 from the  
23 McGovern deposition.

24 THE WITNESS: Okay.

25 ///

Page 127

1 Q And a confidence interval that starts at 1.03  
2 is just barely meaningful; right?

3 A I don't think meaningful is determined by the  
4 confidence level. Perhaps as significant as 3.05 is,  
5 but meaningful, no.

6 Q Okay. But your report was predicated on the  
7 assumption that the odds ratio of 3.8 was accurately  
8 reported in the McGovern paper; right?

9 A It was based on a report in a peer reviewed  
10 paper, correct.

11 Q Okay. And based on the testimony of Dr. Reed  
12 at least -- and there are -- and -- and there are  
13 other documents that Dr. Holford refers to that  
14 corroborate at least his -- his point about there  
15 being one more in -- in HotDog -- based on that and  
16 the calculations, the -- this -- the odds ratio is at  
17 best 2.86; right?

18 A Well, in this -- in this recalculation adding  
19 one more event to each group, it's 2.86, correct.

20 Q Does that give you any pause that adding one  
21 more infection to each group causes the odds ratio to  
22 go from 3.8 to 2.86?

23 A I don't know about giving any pause. But  
24 I've commented before that these events are not -- are  
25 not so common. So it's not surprising that the odds

Page 129

1 BY MR. GORDON:

2 Q Well, let me see if this helps refresh your  
3 recollection. Why don't you -- you know what,  
4 Ms. Conlin pointed out to me before we just broke that  
5 I had marked an exhibit from Mr. Albrecht's deposition  
6 where there was actually writing on it from  
7 Mr. Albrecht. So I didn't copy that.

8 MR. GORDON: So this one, I want you to  
9 have a copy available to you -- to you. So I'm  
10 going to give you Exhibit 6. I will hand you  
11 Exhibit 6, which is the same McGovern paper we've  
12 been talking about, but it just has no writing on  
13 it the way the one in ours did.

14 (The aforementioned document was  
15 marked Exhibit 6 for identification  
16 by the reporter.)

17 BY MR. GORDON:

18 Q And I would like you on Exhibit 6 to turn to  
19 Figure 7, which appears on page 1843.

20 (Witness turning to page.)

21 BY MR. GORDON:

22 Q Does this refresh -- refresh your  
23 recollection as to whether you saw Exhibit 5, this  
24 version of Figure 7 where the infection rate is  
25 reflected as a -- as a moving average as opposed to



Page 166

1 BY MR. GORDON:

2 Q Okay. But what I want to understand is when  
3 you came to the opinion that you offered to the court  
4 on March 30, as I read the report, it -- the McGovern  
5 study is a critical element in how you arrived at your  
6 conclusions. But if I'm -- in fact, that's how I read  
7 it. That doesn't really matter.

8 A Yeah. That's --

9 Q My question to you, because you keep talking  
10 about it -- it's is just part of the data. If you  
11 didn't have the Mc --

12 If you hadn't had the McGovern paper at all,  
13 would you have, based on all the other stuff that  
14 you're talking about, arrived at the same conclusion  
15 on March 30?

16 A The McGovern paper is, at the time I wrote my  
17 report, the sole paper in the peer reviewed literature  
18 offering an estimate of the risk of deep joint  
19 infection associated with the Bair Hugger device.

20 Q So if you hadn't had the McGovern paper, you  
21 would not have reached the conclusions that you  
22 reached --

23 MS. CONLIN: It calls for speculation.

24 BY MR. GORDON:

25 Q -- on March 30; right?

Page 167

1 MS. CONLIN: It calls for speculation.

2 THE WITNESS: I -- I could only -- I  
3 could only say that there would not have been  
4 anybody to -- absent the McGovern paper, to  
5 quantify the magnitude of this.

6 BY MR. GORDON:

7 Q Okay. But you would have still opined that  
8 there was a risk, just you couldn't quantify it?

9 A I just can't answer that question.

10 Q Well, let's approach it from a different  
11 standpoint. You've mentioned now several times that  
12 the McGovern paper was not the only evidence or data  
13 upon which you based your conclusion.

14 Tell me what the other body of -- of data is  
15 that contributed to your opinion.

16 A Well, let me take out my report --

17 Q Sure.

18 A -- and -- and comment on that. I think the  
19 sections lay out the different lines of evidence that  
20 were considered and perhaps --

21 Critically the idea is laid out in Figure 3  
22 on page 21.

23 Q Okay. So table -- that table lists four  
24 sentences; right?

25 A No. I said Figure 3 on page 21.

Page 168

1 Q Oh, Figure 3. I'm looking at page 3.

2 I'm sorry. What page?

3 A 21.

4 Q Okay. Okay. So you -- this is, you say,  
5 "Mechanisms by Which the Bair Hugger Increases Risk  
6 for Joint Infection"; is that right?

7 A That's the title.

8 Q And you have the first two arrows. One goes  
9 to disturbed unit or directional flow. The other goes  
10 to microbial contamination of a surgical field.  
11 Right?

12 A Correct.

13 Q Let's talk about the bottom, microbial  
14 contamination of a surgical field.

15 What do you mean by "microbial  
16 contamination"?

17 A Microorganisms.

18 Q Okay. And what data did you review that --  
19 well, strike that.

20 Am -- am I correct in inferring from your  
21 depiction here in Figure 3 that you believe there are  
22 some evidence that the Bair Hugger device results in  
23 increased microbial contamination of a surgical field?

24 A Well, it is shown that -- the -- the  
25 literature cited shows that -- and -- and also the

Page 169

1 computational fluid dynamics of modeling that there's  
2 increased flow of particles across the surgical field.

3 I believe at least one study -- maybe it's  
4 Moretti [phonetic] -- shows increased numbers of  
5 microorganisms associated with the Bair Hugger  
6 operating and then also the disruption of directional  
7 flow. So those contribute to increased risk of  
8 infection, which is what I've laid out here in  
9 Figure 3.

10 Q You -- you referenced computational fluid  
11 dynamics.

12 I take it you are referring to the  
13 computational fluid dynamics analysis that was done  
14 under contract to Dr. Al Garbashi [phonetic] at the  
15 request of plaintiffs in this case?

16 A That's correct.

17 Q I noticed --

18 MR. GORDON: Let me show you an exhibit  
19 I'm up to 13. Let me show you Exhibit 13.

20 (The aforementioned document was  
21 marked Exhibit 13 for  
22 identification by the reporter.)

23 BY MR. GORDON:

24 Q I noticed in your reference materials you  
25 cited to an unpublished document by Memarzadeh.



1 UNITED STATES DISTRICT COURT  
2 DISTRICT OF MINNESOTA  
3

4 In re Bair Hugger Forced Air ) MDL No. 15-2666  
Warming Products Liability ) (JNE/FLN)  
5 Litigation, ) VOLUME II  
 ) PAGES 211-324  
6  
7  
8  
9  
10  
11  
12

13 VIDEOTAPED DEPOSITION OF JONATHAN SAMET, M.D.  
14 LOS ANGELES, CALIFORNIA  
15 TUESDAY, AUGUST 8, 2017  
16  
17  
18  
19  
20  
21  
22  
23

24 JOB NO. 128394  
25 DORIEN SAITO, CSR 12568, CLR

1 UNITED STATES DISTRICT COURT  
2 DISTRICT OF MINNESOTA

3  
4 In re Bair Hugger Forced Air ) MDL No. 15-2666  
Warming Products Liability ) (JNE/FLN)  
5 Litigation, )  
6 )  
7  
8  
9

10 Videotaped deposition of JONATHAN SAMET,  
11 M.D., taken on behalf of Defendants, at  
12 2001 North Soto Street, 3rd Floor,  
13 Los Angeles, California 90032, commencing  
14 at 8:36 a.m., Tuesday, August 8, 2017,  
15 before Dorien Saito, CSR 12568, CLR.  
16  
17  
18  
19  
20  
21  
22  
23  
24  
25

1 A P P E A R A N C E S :

2 FOR PLAINTIFFS:

3 CIRESI CONLIN  
4 By: JAN CONLIN, Attorney at Law  
By: MICHAEL SACCHET, Attorney at Law  
5 225 South 6th Street  
6 Minneapolis, Minnesota 55402  
7  
8

9 FOR DEFENDANTS:

10 BLACKWELL BURKE  
11 By: COREY GORDON, Attorney at Law  
12 431 South Seventh Street  
13 Minneapolis, Minnesota 55415  
14

15 ALSO PRESENT:

16 JORDAN LEADS, Videographer  
17 MORDECAI BOONE  
18  
19  
20  
21  
22  
23  
24  
25

1 I N D E X

2 WITNESS:	
3 JONATHAN SAMET, M.D.	PAGE
4 EXAMINATION BY MR. GORDON	219, 318
5 EXAMINATION BY MS. CONLIN	314

6 INFORMATION REQUESTED:

7 (NONE)  
8

9 QUESTIONS INSTRUCTED NOT TO ANSWER:

10 (NONE)  
11

12 E X H I B I T S :

13 NUMBER	DESCRIPTION	PAGE
14 Exhibit 20	Orthopedic Reviews 2017; 15 Volume 9:6998 entitled 16 "Forced-air warming 17 discontinued: Periprosthetic 18 joint infection rates drop" 19 by Scott D. Augustine	222
20 Exhibit 21	EHP Commentary "Epidemiology, 21 Public Health, and the 22 Rhetoric of False Positives"	225
23 Exhibit 22	American Journal of 24 Epidemiology "Risk Factors 25 for Wound Infections After Total Knee Arthroplasty" by Steven M. Gordon, et al.	233

1 I N D E X

2 (Continued)

EXHIBITS :		
NUMBER	DESCRIPTION	PAGE
Exhibit 23	Conductive Fabric Warming Beta Site: Reduction in Joint Implant Infections from Ridgeview Medical Center and Clinics	252
Exhibit 24	Email from Mark Albrecht to Scott Augustine with attachments dated November 22, 2015	256
Exhibit 25	RMC Total Joint Infection Rates 2006 Through 2009	259
Exhibit 26	"Predicting bacterial populations based on airborne particulates; A study performed in non laminar flow operating rooms during joint arthroplasty surgery" by Gregory W. Stocks, M.D., et al.	289
Exhibit 27	PLOS One, document entitled "Can Particulate Air Sampling Predict Microbial Load in Operating Theaters for Arthroplasty?" By Marla Luisa Cristina, et al.	293

Page 216

1	I N D E X		
2	(Continued)		
3	E X H I B I T S :		
4	NUMBER	DESCRIPTION	PAGE
5	Exhibit 28	Journal of Hospital Infection	296
6		document entitled "Monitoring	
7		air sampling in operating	
8		theatres: Can particle	
9		counting replace	
10		microbiological sampling?"	
11		by A. Landrin, et al.	
12	Exhibit 29	Journal of Clinical	298
13		Anesthesia document entitled	
14		"Airborne bacterial	
15		contamination during	
16		orthopedic surgery; A	
17		randomized controlled pilot	
18		trial" by Ruken Oguz, et al.	
19	Exhibit 30	Document entitled "Do Forced	300
20		Air Warming Devices Increase	
21		Bacterial Contamination of	
22		Operative Field?" by	
23		McGovern, et al.	
24	Exhibit 31	Augustine Biomedical + Design	305
25		Research Report dated	
		April 4, 2008 by	
		Mark Albrecht	
	Exhibit 32	Kennedy Hodges L.L.P.	309
		document "Bair Hugger Warming	
		and Peri-Prosthetic	
		Infections in Joint	
		Replacement Surgery: A Guide	
		to Product Liability	
		Litigation	

Page 217

1	I N D E X		
2	(Continued)		
3	E X H I B I T S : (Previously marked)		
4	NUMBER	DESCRIPTION	PAGE
5	Exhibit 1	Expert Report of Jonathan M.	221
6		Samet, M.D., M.S. dated	
7		March 30, 2017	

Page 218

LOS ANGELES, CALIFORNIA; TUESDAY, AUGUST 8, 2017  
8:36 A.M.  
-0o0-  
\*\*\*

THE VIDEOGRAPHER: This is the start of  
tape labelled Number 1 of the videotaped  
deposition of Dr. Jonathan Samet in re Bair Hugger  
Forced Air Warming Products Liability Litigation  
in the United States District Court, District of  
Minnesota, Case Number 152666 JNE/FLN.

This deposition is being held at  
2001 North Soto Street, Los Angeles, California,  
on Tuesday, August 8 of 2017 at approximately  
8:36 a.m.

My name is Jordan Leads from TSG  
Reporting, Incorporated, and I am the legal video  
specialist.

The court reporter is Dorien Saito in  
association with TSG Reporting.

Will counsel please introduce yourselves.

MR. GORDON: Corey Gordon on behalf of  
the defendants.

MS. CONLIN: Jan Conlin on behalf of the  
plaintiffs. With me here today is Mike Sacchet.

MR. GORDON: Also -- also here with me

Page 219

today is Mordecai Boone from the 3M office of  
legal counsel.

THE VIDEOGRAPHER: All right. Thank you.  
Would the court reporter please swear in  
the witness.

THE REPORTER: Would you raise your right  
hand.

THE WITNESS: (Complies.)

THE REPORTER: Do you so state under  
penalty of perjury that the testimony you shall  
give in your deposition shall be the truth, the  
whole truth, and nothing but the truth?

THE WITNESS: Yes.

\*\*\*

JONATHAN SAMET, M.D.,  
having been duly administered an oath  
in accordance with CCP 2094, was  
examined and testified as follows:

\*\*\*

#### EXAMINATION

BY MR. GORDON:

Q Good morning, Dr. Samet.

We -- we met about a month ago when we started  
your deposition.

And I guess the first thing I want to find out

1 on this, but I want to -- want you to recall the  
2 discussion of Professor Holford's calculation of the  
3 odds ratio based on Dr. Reed's testimony that there  
4 should have been one additional deep joint infection in  
5 each of the cohorts that were considered and  
6 Dr. Holford's calculation came up with an odds ratio of  
7 2.86.

8 Do you recall that?

9 A I recall that, yes.

10 Q And I read your deposition again last night,  
11 and I'm pretty sure that -- what your answer is, but  
12 I -- it was -- it was -- there's just enough of a  
13 question in my mind that I want to ask.

14 Do you have any reason to quarrel with  
15 Dr. Holford's analysis of that 2.86 odds -- odds ratio?

16 A Well, I think it's a straight -- the  
17 calculation of the odds ratio itself is a rather  
18 straightforward matter, I think.

19 The basis for Dr. Reed's comment that the  
20 data set might have this error in it, I'm not sure.  
21 I'm a little bit -- I don't know the basis for that  
22 comment.

23 But the computation of adding one to each of  
24 the appropriate cells is a rather simplistic matter.

25 Q Well, do you have any basis for questioning

1 Dr. Reed's testimony that there should have been one  
2 additional infection added to --

3 A Well --

4 Q -- each cohort?

5 A Of course I -- I don't. I simply don't know  
6 what the basis for his suggestion is.

7 Q Okay. Do you need the -- the basis to factor  
8 in his sworn testimony on that point into arriving at  
9 your opinions?

10 A Well, I will only give a more general  
11 response. That when one suggests that there's an  
12 error in the database, it's usually with some specific  
13 justification that a correction is made.

14 Q All right. And the reason I'm asking you this  
15 is because you -- you once again mentioned a 3.8 odds  
16 ratio and -- and you discussed that earlier in your  
17 deposition.

18 Based on Dr. Reed's testimony and  
19 Dr. Holford's recalculation, the odds ratio at most  
20 is -- was 2.86; correct?

21 MS. CONLIN: I'm going to object --

22 THE WITNESS: Yeah.

23 MS. CONLIN: -- to the form of the  
24 question.

25 THE WITNESS: If that's the specific

1 number. I'd have to go look to verify that it's  
2 2.86. But it's around -- it's around that value.  
3 BY MR. GORDON:

4 Q All right. So in -- in holding the opinions  
5 that you hold today and are prepared to offer in court,  
6 is your opinion based on your assumption that the  
7 McGovern study stands for the proposition that -- that  
8 there is a 3.86 odds -- odds ratio or something else?

9 A Well, the -- relying on the published peer  
10 reviewed paper, the odds ratio that stands in the  
11 literature is 3.8.

12 Q And my question, though, is, Is that what  
13 you're relying on in the opinions you hold as you sit  
14 here today?

15 A Well, as stated in my expert report, I  
16 addressed the issue of the potential for confounding  
17 to lead to an estimate of 3.8.

18 Again, I think if -- if one were to say could  
19 the estimate be 2.8 based on Reed's comment, I think  
20 the same issue still stands around the potential for  
21 confounding to generate a relative risk that is  
22 roughly triple the -- I'm sorry. Yeah -- tripling the  
23 risk for deep joint infection.

24 Q So whether it's 2.8 or 3.8, it doesn't in any  
25 way impact your opinions?

1 A You know, again, the point is that you have  
2 to postulate a set of uncontrolled confounding factors  
3 that could lead to such strong association.

4 Q Okay. And just looking at Exhibit 22, one --  
5 there was a -- a -- at least a statistically  
6 significant association with a particular surgeon and a  
7 particular -- and a particular cohort of patients,  
8 their -- their ASA class; right?

9 A Well, the paper shows a particular positive  
10 interaction between being -- having higher ASA class  
11 and having been operated on by a particular surgeon,  
12 yes.

13 Q And neither the surgeon-specific factors or  
14 patient-specific factors were -- were considered in the  
15 McGovern paper; correct?

16 MS. CONLIN: Asked and answered.

17 THE WITNESS: Well, again, I -- I think I  
18 commented. The same institution in a very short  
19 temporal separation of the two time periods.

20 BY MR. GORDON:

21 Q Let's go to the Augustine paper, if you would.

22 Was that Exhibit --

23 MS. CONLIN: 20.

24 BY MR. GORDON:

25 Q 20. And your -- based on what Dr. Augustine

Page 312

1 airflow, those mechanistic things, that Dr. Augustine  
2 and his employees also conducted research that  
3 demonstrated that the Bair Hugger didn't actually  
4 increase bacteria at the surgical site and never  
5 published it, and Dr. Augustine hired a group of  
6 plaintiffs' lawyers and drafted this guide to product  
7 liability litigation in their name, set up a website  
8 ostensibly in the name of the plaintiffs' law firm,  
9 sent out the guide to other plaintiffs' law firms in an  
10 effort to encourage litigation.

11 If you -- if all those facts were assumed to  
12 be true, is that something that you, as a professional  
13 scientist, epidemiologist, public health expert -- is  
14 that something that you -- you'd feel comfortable  
15 associating yourself with?

16 MS. CONLIN: I'm going to object to the  
17 form of the question both based on the fact that  
18 it misstates the record and it misstates the facts  
19 and makes assumptions that are not borne out by  
20 the evidence in this case.

21 THE WITNESS: I'm not going to ask you to  
22 repeat the question, but...

23 And, again, I have not seen this  
24 document. I do find it difficult, which I think  
25 you implied, that an entire body of literature in

Page 313

1 this sense has been both created and -- and  
2 legitimate investigators like McGovern and Reed  
3 somehow were contaminated by a single individual.

4 So I -- I think that's the -- the  
5 scenario that you laid out with your list of  
6 assumptions. I really can't comment on it because  
7 I don't have the basis for -- for doing so.

8 But I find it somewhat implausible to  
9 think that, you know, legitimate academics with  
10 strong records would allow their work to be  
11 subverted, if you will.

12 BY MR. GORDON:

13 Q It's happened, though, hasn't it, in the past?  
14 We talked about Dr. Wakefield [phonetic] and all the  
15 other co-authors on his Lancet papers.

16 A I'm not sure that Dr. Wakefield was a  
17 legitimate academic. Unfortunately, his co-authors  
18 signed onto that particular paper.

19 Q By legitimate academics, I was referring to  
20 some of the co-authors of Dr. Wakefield's Lancet paper.

21 A Certainly there were people who had solid  
22 reputations who were co-authors on that paper.

23 MR. GORDON: Let's take a quick break.  
24 See if I have --

25 THE VIDEOGRAPHER: The time is 10:53 a.m.

Page 314

1 We are off the record.

2 (A brief recess was taken.)

3 THE VIDEOGRAPHER: We are back on the  
4 record. The time is 10:56 a.m.

5 MR. GORDON: Dr. Samet, I have a number  
6 of other things I can -- can take time asking you  
7 about. But I understand you have a very narrow  
8 time window. So out of respect to you and your  
9 other commitments, I'm going to pass the witness.

10 THE WITNESS: Great. Thank you very  
11 much.

12 MS. CONLIN: Thanks.

13 \*\*\*

#### 14 EXAMINATION

15 BY MS. CONLIN:

16 Q So I just have a couple questions, Doctor.  
17 You are relying in part of on Dr. Jarvis and  
18 Dr. El-Ghobashy [phonetic]; is that correct?

19 MR. GORDON: Object to the form of the  
20 question.

21 THE WITNESS: Yes.

22 BY MS. CONLIN:

23 Q Okay. And with respect to this issue of  
24 particulates being a proxy for CFUs, were you aware the  
25 PJI consensus in 2016 says that there is a correlation

Page 315

1 between the two?

2 MR. GORDON: Object to the form of the  
3 question.

4 THE WITNESS: Yes, I am aware.

5 BY MS. CONLIN:

6 Q And you're aware that Dr. Jarvis testified to  
7 that as well; correct?

8 MR. GORDON: The same objection.

9 THE WITNESS: Yes, I am.

10 BY MS. CONLIN:

11 Q Okay. One of the studies that you mentioned  
12 in your report, the Moretti [phonetic] study, did that  
13 show direct evidence of significant increase in  
14 bacteria or CF use in the Bair Hugger?

15 MR. GORDON: The same objection.

16 BY MS. CONLIN:

17 Q I believe it's on page 12 --

18 A Let me --

19 Q -- 13 of your report?

20 A Let me find my report. But that rings a  
21 bell, and it's perhaps what I was looking for.

22 I'm sorry. Page --

23 Q I think it's 13, Doctor.

24 (Witness turning to page.)

25 THE WITNESS: That's correct.